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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/615606
Filing Date: 07/13/2000
Appellant(s): Abad et al

Thomas E. Holsten
Holly L. Prutz
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 06/15/2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) ***Status of Claims*** The statement of the status of the claims contained in the brief is correct.

(4) ***Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) ***Summary of Invention***

The summary of invention contained in the brief is correct.

(6) ***Issues***

The appellant's statement of the issues in the brief is mostly correct.

(7) ***Grouping of Claims***

Examiner disagrees with Appellant's statement that all of the claims at issue do not stand or fall together.

(8) ***Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) ***Prior Art of Record***

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 101/ 112-1 (enablement)

A. Claims 1, 8-13 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility. The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The claims are drawn to substantially purified nucleic acid molecule comprising of or consisting of sequence SEQ ID NO. 2, wherein the nucleic acid encodes a soybean protein or a fragment of a soybean protein. No open reading frame, start/stop codons, or encoded protein is identified in the specification for SEQ ID NO. 2. Even though specification asserts that SEQ ID NO. 2 is a cDNA, the

claimed sequence does not have either start or stop codons and it is not possible to deduce from the sequence itself whether it represents a fragment of a DNA or cDNA. In the absence of start/stop codons it is not clear what, if any, is being encoded by the sequence. There is no information about any soybean protein or fragment thereof encoded by the SEQ ID NO. 2. Neither there is any other identifying information associated specifically with SEQ ID NO. 2. The specification does not list any potentially homologous prior art sequences for SEQ ID NO. 2.

General uses of polynucleotides set forth in the specification, as filed, include acquiring genes, identifying polymorphisms, determining plant traits, and DNA mapping. None of these is considered to be specific and substantial in view of the limited information provided in the specification. No plant traits are attributed to SEQ ID NO.3. No complete gene is disclosed for SEQ ID NO. 2. No DNA maps or chromosomal locations are identified. No polymorphisms are identified. The specification does not disclose how a polymorphism would be recognized by those of ordinary skill in the art given the incomplete sequences disclosed. Further research and experimentation would be required to identify a full length sequence that encoded a full-length protein, to characterize the chromosomal location, to determine the presence of polymorphisms, and to determine any associated plant traits. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define

a "real world" context or use. Similarly, the other listed and asserted utilities are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid compounds such that another non-asserted utility would be well established for the compounds.

Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

B. Claims 1, 8-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, first paragraph (written description).

C. Claims 1, 8,10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1, 8, 10-13 are directed to a nucleic acid molecule comprising SEQ ID NO. 2 "that encodes a soybean protein or fragment thereof". SEQ ID No. 2 is asserted to be a cDNA sequence. However, it is not possible to deduce from the sequence itself whether it represents a fragment of a DNA or cDNA. The polynucleotide consisting of the exact sequence SEQ ID NO. 2 meets the provision of written description. However, the claims encompass gene sequences, encoding sequences and so forth. None of these products meet the written description provision of 35 USC 112, first paragraph as there is no description of other elements included in DNA, such as non-coding, regulatory regions, etc. The specification fails to describe any open reading frames, start/stop codons, or encoded proteins for any SEQ ID NO, SEQ ID NO. 2 in particular. As such, these nucleic acid molecules are not described. At best, the SEQ ID NO. 2 may include a sequence encoding a fragment but not a full length protein. Note that there is no

start codon ATG in the SEQ ID No. 2. The specification provides insufficient written description to support the genus encompassed by the claim.

In regard to claims 8, 10-13, which do not have limitation of encoding a soybean protein, the claims still have "comprising" language that reads on a polynucleotide encoding a full-length protein; applicants clearly are not in possession of such polynucleotide(s).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of nucleic acid consisting of sequence of identified SEQ ID No, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016.

D. Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides having less then 100% degree of identity with SEQ ID NO. 2. The specification discloses SEQ ID NO. 2 which encodes a soybean protein. Polynucleotide SEQ ID NO. 2 itself meets the written description provision of 35 USC 112, first paragraph. However, claims 13-16, drawn to nucleotide sequences having less than 100% identity to the elected SEQ ID No. 2, does not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less then 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not. Therefore, sequence similarity result in an unpredictable and therefore unreliable correspondence between the newly discovered sequence and a similar biomolecule of known expression or function. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to encode proteins belonging to the same species (soybean, for example).

The specification provides insufficient written description to support the genus encompassed by the claims.

(11) Response to Argument

Claim Rejections - 35 U.S.C. § 101/ 112-1

Appellants assert that the claimed invention meets the utility and enablement requirements because they have disclosed "nucleic acid molecules which, in their current form provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism." The examiner does not agree that the nucleic acid molecules provide any specific benefit to the public in their current form; rather, it requires further experimentation to determine whether such a benefit can be found.

The Examiner agrees that the "The threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit," with the proviso that the benefit be "identifiable" in the original disclosure either as a specific assertion or being readily apparent from the disclosure (i.e. well established). The Examiner also agrees "the invention must have specific, i.e. not vague or unknown benefit" and "must provide a real world, i.e. practical or substantial, benefit." Whether the instant application has met this burden is the subject of this section of the appeal.

Appellant argues, p.6-9, that the claimed nucleic acid molecules can be used to detect the presence and/or identity of polymorphisms, as hybridization probes for expression profiling, for genetic mapping or monitoring gene expression, as antisense inhibitors, and as a molecular marker. The Examiner maintains that further research is required for such uses.

MPEP 2107 states that:

> On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> (B) A method of treating an unspecified disease or condition;
>
> C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
>
> (D) A method of making a material that itself has no specific, substantial, and credible utility; and
>
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

All of these situations closely match appellant's disclosed uses. They do not define substantial utilities. Further, MPEP 2107 states

> An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

The instant specification sets forth no such correlation for any such conditions.

Appellant, arguing use of nucleic acids for detecting polymorphisms, compares use of the claimed products to the use of a gas chromatograph (page 7,

first full paragraph). MPEP 2107 in discussing research tools sets forth the following:

> Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

The gas chromatograph example set forth by appellant, particularly as discussed in Footnote 4 on page 7, is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated, and calibrated to ensure accurate results. Those skilled in the art use gas chromatographs to analyze both known and unknown compounds. When the compound is unknown, the results obtained are compared to results for known compounds, e.g. standards. Appellants did not design the claimed nucleotide sequences for any particular purpose. They merely isolated them. They have not tested, evaluated, or calibrated the claimed nucleotide sequences for any particular use. Sampling for the presence or absence of chlorine in a crude oil sample is not analogous to the present situation. The presence or absence of chlorine in a crude oil sample has a known meaning based upon prior research. Absent establishment of this association between presence of chlorine and destruction of catalyst, the presence or absence of chlorine in a sample would not provide any useful information to the refinery manager. Likewise, the presence or absence of any of the claimed nucleotide sequences in a

sample (or polymorphisms thereof) has no meaning absent some association. Further experimentation is required to determine what that meaning or association might be.

In addition, this gas chromatograph analogy fails to address Appellants' own definition of the term polymorphism. The specification, p. 50, first paragraph, defines "polymorphism" as "a variation or difference in the sequence of the gene or its flanking regions that arises in some members of a species." It follows from this definition that if there is no "variation or difference in the sequence of the gene or its flanking regions" among "members of a species," then no polymorphism exists, i.e. a polymorphism is absent, in this region of the genome. A "polymorphism" is a collective concept defined by at least two variants (or alleles) found within members of a species collectively. Thus, one detects the *presence* of a polymorphism by analyzing multiple members of the species, i.e. analyzing a population. While one can detect the absence (or presence) of a specific allele of the polymorphism in a specific individual member of the species, one cannot detect the *absence* of a polymorphism *per se* based on one individual alone. The absence of a particular allele necessarily means that a different allele is present. The specification fails to disclose a specific and substantial utility for the claimed invention in the capacity of detecting polymorphisms, because it does not disclose whether the claimed nucleic acid molecules can, in fact, be used to detect any polymorphism whatsoever. Thus, the specification leaves open the possibility that there may be no polymorphism to detect. With respect to the gas chromatograph analogy, one can only detect the absence of a compound, such as chlorine, in a sample, *if* it was already known that chlorine could, in fact, be detected by the gas chromatograph were it present in the sample.

The specification generally teaches using the claimed polynucleotides to identify a polymorphism, but fails to teach that a polymorphism could in fact be detected, or a specific polymorphism that could be detected. The specification generally teaches using a polymorphism, detectable with the claimed nucleic acid molecules, as a molecular marker for a linked trait of interest, but fails to teach either the polymorphism or the trait of interest. The court in *Kirk* (at page 53) held:

> We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

The specification (p. 50, first paragraph) defines "polymorphism" as "a variation or difference in the sequence of the gene or its flanking regions that arises in some members of a species" (emphasis added). The following pages of the specification discuss various types of sequence polymorphisms and how they are detected. It is noted that on page 53, last paragraph, the specification states, "By correlating the presence or absence of it [a polymorphism] in a plant with the presence or absence of a phenotype...". Thus, the specification acknowledges that further analysis is required to determine a use for a polymorphism even assuming one is found. A change of phenotype and correlation with phenotype must be found; linkage analysis must be performed. Even to determine whether a polymorphism exists at a specific chromosomal location requires hybridization to at least two individual chromosomes, and generally involves analyzing genomic DNA

from multiple members of a species; the specification discloses no such analysis. The specification fails to disclose: 1) whether the claimed nucleic acid molecule can in fact detect a polymorphism, or even whether such a polymorphism exists; and 2) at least one specific example of at least one of the types of polymorphisms described in the specification. The specification does not disclose any utility in this context for a nucleic acid molecule or EST that can NOT detect a polymorphism. Therefore, using the claimed invention to first determine whether or not the claimed nucleic acid molecule can, in fact, detect a polymorphism *is* to determine whether or not the claimed invention has a utility that requires detecting a polymorphism, i.e. it is "use testing" and not substantial. Since the specification fails to identify even one specific polymorphism that can be detected with the claimed nucleic acid molecule, the specification fails to show any specific correspondence between the disclosed general utility and the claimed subject matter, regardless of any specific application requiring detection of polymorphisms.

With respect to use of nucleic acids as probes in microarrays, specification does not associate any of the claimed sequences with any trait of interest. Contrary to appellant's assertions, further experimentation is required to identify a "real world use." A negative result to such a screen tells what the nucleic acid is not and cannot be used for. A positive result to such a screen requires further experimentation to determine what, if anything, such a change means. It is not an immediate benefit except in the sense to indicate that further research might yield a "real world use."

Appellants argue that the claimed nucleic acid molecules have utility as "probes for other molecules or as a source of primers." Appellant argues that the claimed nucleic acid molecules are useful to detect or measure nucleic acid

molecules that possess a certain level of structural relatedness to the claimed nucleic acid molecules, the level of relatedness being defined by hybridization to the claimed nucleic acid molecules. However, the specification discloses *no* nucleic acid molecule that hybridizes with the claimed nucleic acid molecules that does *not* consist or comprise SEQ ID NO:2 or its complement. In order for hybridization between two nucleic acid molecules to occur, they must share at least some nucleotide sequence that is fully complementary. The length of fully complementary sequence required to detect hybridization depends primarily on the stringency of the specific hybridization conditions employed, the lower the stringency the shorter the length of fully complementary sequence required. The specification also fails to disclose any hybridization conditions required for detecting nucleic acid molecules that do *not* contain the nucleotide sequence of SEQ ID NO:2 or its complements (other than subsequences of SEQ ID NO:2), in addition to failing to disclose any source for such nucleic acid molecules.

It is also noted that Appellant offers some arguments about utility of corresponding mRNA (footnotes 1,2 on p. 6,7). However, a utility of corresponding mRNA is not at issue as it has not been addressed previously during the prosecution of the application.

Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* (p.8) in support of their position that utility has been established. However, this decision is with respect to a mechanical device and not a laboratory reagent or research tool. Furthermore, applicant mischaracterizes the findings in this decision. This decision concerned claim interpretation and the CAFC found that the district court had erred in their interpretation of what the claim embraced and thus what was required to establish

utility. The claimed device was found to fulfill the stated objective of mounting a stylus by the CAFC. These facts do not correspond to the instant specification

With respect to use of the claimed nucleic acids to obtain other nucleic acid molecules, the specification does not indicate that any such nucleic acid molecules *had been* obtained, nor does it describe any characteristics possessed by such nucleic acid molecules. As to whether such molecules could, in fact, be obtained, the Office can neither prove nor disprove the assertion because the Office does not have laboratory facilities. At the time the application had been filed, future experimentation on the part of one skilled in the art would have been required to determine which, if any, other plant species contained nucleic acid molecules that could have been obtained using the claimed invention, and under what experimental conditions.

With respect to using the claimed nucleic acid molecules to initiate a chromosome walk, such as to isolate a promoter of the corresponding gene, the specification fails to disclose any characteristics of the corresponding promoter, or any other promoter within "chromosome walking" distance; neither structural characteristics, by which the promoter might be identified, nor functional characteristics, by which a specific and substantial use for the promoter might be determined.

Even assuming *arguendo* that the corresponding promoter exists is no more guidance for its isolation, and eventual use, than knowing that a haystack contains a needle - at least one is presumed to know what the needle looks like. Also, the specification does not disclose the distance or direction one has to walk on a chromosome from the corresponding location to reach the corresponding promoter. Thus, starting the walk at the corresponding chromosomal location is no more help

in identifying the promoter than is picking a specific location in a haystack to start looking for a needle when one does not know where the needle is relative to the starting location. Initiation of a chromosome walk at the corresponding chromosomal location is considered non-specific because any EST would serve the purpose for isolating an uncharacterized promoter, since any chromosomal location is expected to be linked to a promoter. The specification fails to disclose sufficient characteristics of the corresponding promoter, such as its sequence or precise location relative to the genomic location corresponding to the claimed nucleic acid molecule, to inform one of what the corresponding promoter is or when it has been isolated. For example, a nucleotide sequence is identified during the chromosome walk as a putative promoter by sequence analysis, is then subcloned into operable linkage with a reporter gene and transfected into an appropriate cell, but found not to express the reporter gene in the cells. This result could mean the putative promoter: is not truly a promoter, i.e. a false positive; is not the corresponding promoter; or is incomplete, i.e. lacked additional sequence elements required for promoter activity in the seed pod cells. Substantial utility means that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate* benefit to the public," *Nelson v. Bowler*, 206 USPQ2d 881, 883 (CCPA 1980) (emphasis added). Since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one skilled in the art that it has been isolated, there can be no "*immediate* benefit to the public" in using the claimed nucleic acid molecule in this capacity; "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion," *Brenner* at page 696.

With respect to the "real world" value of ESTs in general (Brief, page 11), it is asserted that there is "no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed 'real world' value to such nucleic acid molecules." It is unclear as to what evidence Appellants are alluding. The evidence supplied by Appellants shows that a multimillion dollar industry has arisen surrounding buying and selling EST databases and clones, not that anyone in this industry has bought or sold the claimed subject matter. It is noted that simply because a product, such as an EST sequence database or clone library, is bought and sold does not mean it has patentable utility.

With respect to credibility, appellant is reminded that in order to meet the requirements of 35 USC 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of well established utility, which would presume that the utility was credible). The claims have been rejected because 1) the specification fails to disclose at least one utility that is both specific and substantial, and 2) no convincing evidence has been presented to show that an EST, for which only its nucleotide sequence and source have been disclosed, has a well established utility.

Appellant argues that claims 8, 10-13 have separate patentability by submitting that "Examiner provides no evidence that the sequence [SEQ ID No. 2] is not full-length". Instead of meeting the burden to demonstrate the presence of an open reading frame, appelant accuses Examiner in not doing it himself. Note, however, that a mere look at SEQ ID No. 2 indicates absence of ATG codon, characteristic for the beginning of an open reading frame, at the beginning of the sequence. Further, appelant again discusses use of claimed polynucleotides as

probes to detect polymorphism; this potential utility (or lack thereof) is addressed in full in the preceding paragraphs here.

The brief does not appear to directly argue for a well established utility for the claimed invention; however, the arguments concerning the commercial value of ESTs in general (brief, pages 11,12) may implicitly be directed to a well established utility for any EST in general, and the claimed nucleic acid molecules in particular. However, such evidence is not relevant to 35 USC 101.

Finally, appellants argues that claims 8-13 are separately patentable as compared to claim 1. The only difference of claims 8-13 in regard to their utility is that they do not have the limitation of encoding a soybean protein. However, appellant does not offer any additional reasons for existence of utility of the same polynucleotide SEQ ID NO. 2 as claimed in claim 1 when this polynucleotide SEQ ID NO. 2 is not related to a soybean protein.

B ***Claim Rejections - 35 U.S.C. § 112-1 (enablement)***

Claim 1, 8-13 are also rejected under 35 U.S.C. § 112, first paragraph. Since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons discussed above, one skilled in the art would not know how to use the claimed invention.

The Examiner maintains that the uses asserted for the claimed invention are methods where the claimed invention is, itself, an object of scientific study, e.g. to determine whether the corresponding genomic DNA of soybean contains a polymorphism that can be detected with the claimed invention. The specification cannot enable or tell how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. The Examiner maintains that there is no patentable utility for the claimed invention for the reasons set forth above and thus the claims are not enabled.

Claim Rejections - 35 USC § 112, first paragraph (written description).

There are two "written description" rejections of record; the first addressing "comprising" language, and the second - addressing "% identity" language. Appellant provides arguments only regarding the first "written description" rejection.

C. In discussing the alleged lack of written description for polynucleotides "comprising" SEQ ID NO. 2, appellant addresses mostly description of vectors, cells, chromosomes (section D(1), pages 15-17). The issue, however, is the lack of description of polynucleotides comprising SEQ ID NO. 2, and not of the vectors, cells, etc, containing said polynucleotides.

Appellants argue that they have provided the nucleic acid sequence required by the claims, i.e., SEQ ID NO. 2 and vectors comprising these nucleotide sequences, and therefore have established possession of the claimed invention. The claimed invention, which is drawn to a polynucleotide comprising the above SEQ ID NO. 2, when the specification only discloses a partial sequence, as well as

partial open reading frame, effectively encompasses a full-length cDNA sequence comprising an open reading frame. While it is acknowledged that Appellant need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that comprises instant SEQ ID NO. 2, and additional sequences of any size and sequence, not just vector backbones. Clearly, at the time of filing, Appellant was not in possession of genomic materials that contain the common EST fragment, which are embraced by the open-ended claims.

Appellant further argues (section D(2), pages 17-18) that SEQ ID NO. 2 is a sufficient core structure do describe the genus of polynucleotides comprising SEQ ID NO. 2. One skilled in the art would reasonably conclude that the claims embrace full length mRNAs, cDNAs and genomic sequences, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising the claimed SEQ ID NO. 2, and no other indication that would suggest Appellant possessed them.

Appellant further argues (section D(3), page 18) that claims 8, 10-13 are not separately patentable because they do not recite limitation of encoding soybean protein. However, the claims still have "comprising" language that reads on a polynucleotide encoding a full-length protein; applicants clearly are not in possession of such polynucleotide(s). Examiner does not argue that the particular nucleic acid having sequence SEQ ID No. 2 was obtained from soybean; rather, the rejection is directed to lack of written description for polynucleotides "comprising" SEQ ID No. 2.

The basic question upon which Appellants and the Examiner disagree is whether the disclosure of a partial sequence of nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence.

As stated in University of California v. Eli Lilly and Co. at page 1404:

> An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties" not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1 164, 1 171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself "

Id. at I 170, 25 USPQ 2d at 1606.

That Appellants claims embrace nucleic acid molecules that encode a corresponding protein, is clearly evident from the claim language chosen. The court in University of California v. Eli Lilly and Co., at page 1405, further noted regarding generic claims that a written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, or chemical name" of the claimed subject matter sufficient to distinguish it from other materials. In the instant case, the only species specifically enumerated is the nucleic acid of SEQ ID NO. 2. The specific embodiments that in addition to these sequences include nucleic acids that will allow the corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence has not been disclosed. Clearly, the specification would not show one skilled in the art that the these desired subcombinations were possessed by Appellant, and thus the embracing genus was also not possessed.

For the above reasons, it is believed that the rejections should be sustained.

Respectively submitted,

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